REMARKS

Applicants' remarks are in response to the Office Action mailed September 14, 2004. Enclosed herewith is a Petition requesting a three-month extension of time for resetting the deadline for responding to the Office Action from December 14,2004 to and including March 14, 2005.

In the Office Action, claims 1-35 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Errico et al., U.S. Patent No. 5,575,792 ("*Errico*") in view of Le Couedic et al., U.S. Patent No. 6,368,320 ("*Le Couedic*").

The Examiner essentially contends that *Errico* discloses all the recitations included within independent claims 1, 12, 25 and 35 which it is cited against except that the Examiner acknowledges that *Errico* does not teach a connector having a first inwardly deformable portion integral with a second portion and a clamping means wherein the connector is arranged so that, when the clamping means loads the connecting member in the second housing in the direction of the axis, the connecting member loads the seat to inwardly deform the first portion and immobilize the head therein. However, the Examiner contends that *Le Couedic* in a similar art, teaches such a recitation and further argues that it would have been obvious to one of ordinary skill in the art at the time the present invention was made, to modify the connector and clamping means as taught by *Le Couedic* with the device of *Errico* to render the independent claims of the present invention obvious and, thus, unpatentable.

Newly-amended independent claims 1, 12, 25 and 35 all now include a recitation directed toward the second housing or second portion having a U-shaped opening with an open end remote from the first housing. The U-shaped opening of the second housing enables a rod, *i.e.*, connecting member, to be top-loaded

into a connector along the axis of the clamping means. This is highly beneficial in a situation during surgery where the bone anchor or screw has already been mounted to a vertebral body or such and is disposed within a portion, *i.e.*, first housing, of the connector. The U-shaped configuration of the second housing having an open end remote from the first housing, enables the rod to be pushed from above into the second housing of the connector, as opposed to having to slide or translate the connecting member in a direction perpendicular to the screw anchored in the vertebral body. Such a configuration would require a much larger working space for the surgeon to translate the connecting member into the connector and may also cause damage of adjacent tissue and bones as the rod is translated perpendicular to the screw.

As mentioned before, the Examiner further asserts that *Errico* discloses some of the recitations of the independent claims in the present application and that when combined with *Le Couedic* the combination renders the claims of the present invention obvious and unpatentable. Applicants respectively traverse the Examiner's contention and assert that *Le Couedic* is not combinable with *Errico*.

Errico, as acknowledged by the patent Examiner, does not teach a clamping means, wherein the connector is arranged so that when the clamping means is loaded to the connecting member in the second housing in a direction of the axis, the connecting member loads a seat integral with the connecting member to inwardly deform the first portion and immobilize the head therein. Additionally, *Errico* requires that the clamping means includes a two-part locking element such as that as shown in FIG. 11 of *Errico*. First, a locking ring 330 is placed about a coupling element 400 and translated downward to clamp a screw within the coupling element. Once the rod 250 is in place within the coupling element, a second locking element, top

locking nut 235, is threaded on the upper portion 406 of the coupling element 400. The lower surface 238 of locking nut 235 seats against the top of rod 250. As nut 235 rotates, and descends relative to the coupling element 400, the rod 250 is driven downward. This motion forces the locking ring 330 to translate downward along the lower portion 402 of the coupling element 400 and subsequently causes the locking ring 330 to inwardly deflect the lower portion of the coupling element about the head of the screw.

The locking device of *Le Couedic* includes a single locking element, screw 42, which urges a cross member 50 towards a jaw 36. Jaw 36 is then compressed so as to lock rod 48 within jaws 36 of connector 2. The cross member of *Le Couedic* does not have to be received from above within the coupling element.

Le Couedic is not combinable with *Errico* because if you substituted the clamping element of *Le Couedic* with the clamping element of *Errico*, the *Errico* reference would not work for its intended purpose, which is to have the locking ring 330 inwardly deform the lower portion of the coupling element 400. This is because the clamping element of *Le Couedic* includes a screw 42 urging a cross member 50 downward so as to deform the lower portion of a connector about longitudinal rod 48. By substituting the clamping element of *Errico* with the clamping element of *Le Couedic*, you effectively eliminate the locking ring required in *Errico*. Additionally, without the locking ring 330, the coupling element 400 could not be deformed.

Additionally, *Le Couedic* is designed to have the cross member 54 positioned within the connector 2, with the connector slid or pushed onto longitudinal rod 48. *Le Couedic* does not have a U-shaped opening which is open at one end remote from the first portion of the connector. Therefore, a longitudinal rod cannot be top loaded and thus solve one of the problems the present invention is deigned to solve.

There is no suggestion in *Errico* that the locking ring could be eliminated by making the coupling element deformable. In *Errico*, the locking ring is at the heart of his clamping system and thus there is no incentive to combine the reference with *Le Couedic* to eliminate the ring. If the proposed modification or combination of the prior art would change the principle of operation of the prior art being modified, then the teachings of the references are not sufficient to render the claim prima facie obvious. In re *Ratti* 270 F.2d 810, 123 U.S.P.Q. 349 (CCPA 1959). Furthermore, *Errico*'s connecting rod is introduced from the top and *Le Couedic* is introduced from the side. The set screw in *Errico* can be used to orally move the rod onto the connector seat which is not the case in *Le Couedic* where the rod must be moved into position horizontally on the seat prior to the screw being tightened. Thus, the problem being addressed by the two references are different which eliminates the incentive to combine the references.

Applicant has amended the claims to make it clear that the screw and rod move in the same axial direction towards the connector seat.

Applicants therefore request that independent claims 1, 12, 25 and 35 are in condition for allowance and should be deemed patentable. Additionally, dependent claims 2-11, 13-24 and 26-34 all include the limitations from the claims from which they depend and therefore should also be deemed to be in condition for allowance.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that the Examiner telephone Applicants'

attorney at (908) 654-5000 in order to overcome any additional objections which the Examiner might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: March 11, 2005

Respectfully submitted,

By _____

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